

WO0028921

Publication Title:

Coiled-sheet stent-graft with exo-skeleton

Abstract:

A stent-graft having an exo-skeleton attached to a tubular graft, the tubular graft having a peripheral wall defining a lumen therein extending between first and second ends. The exo-skeleton may assume contracted and enlarged conditions, and includes one or more serpentine elements, each extending both peripherally and axially along at least a portion of the peripheral wall. Coiled-sheet stents are provided on the ends of the tubular graft for anchoring the ends within a body passage. Each serpentine element is a zigzag structure extending peripherally about the peripheral-wall, with a plurality of serpentine elements distributed axially along the peripheral wall. The serpentine elements are individually attached to the peripheral wall and/or connector elements may extend between adjacent serpentine elements. Alternatively, each serpentine element may define a generally sinusoidal shape

2f1

extending axially along the peripheral wall. The tubular graft may have a bifurcated end from which a tubular graft extension segment may extend and to which a docking limb may be attached. A plurality of serpentine elements may also be attached to the extension segment and the docking limb

Data supplied from the esp@cenet database - <http://ep.espacenet.com>



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁷ : A61F 2/06</p>	<p>A2</p>	<p>(11) International Publication Number: WO 00/28921 (43) International Publication Date: 25 May 2000 (25.05.00)</p>
<p>(21) International Application Number: PCT/US99/26389 (22) International Filing Date: 8 November 1999 (08.11.99) (30) Priority Data: 09/192,977 16 November 1998 (16.11.98) US (71) Applicant: ENDOTEX INTERVENTIONAL SYSTEMS, INC. [US/US]; 10231 Bubb Road, Cupertino, CA 95014 (US). (72) Inventors: KHOSRAVI, Farhad; Apartment 212, 1700 De Anza Boulevard, San Mateo, CA 94403 (US). PATEL, Himanshu, N.; 1114 Nevada Avenue, San Jose, CA 95125 (US). FRANTZEN, John, J.; 20 Westcliff, Laguna Nigel, CA 92677 (US). (74) Agent: ENGLISH, William, A.; Lyon & Lyon LLP, Suite 4700, 633 West Fifth Street, Los Angeles, CA 90071-2066 (US).</p>		<p>(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>Without international search report and to be republished upon receipt of that report.</i></p>
<p>(54) Title: COILED-SHEET STENT-GRAFT WITH EXO-SKELETON</p> <p>(57) Abstract</p> <p>A stent-graft having an exo-skeleton attached to a tubular graft, the tubular graft having a peripheral wall defining a lumen therein extending between first and second ends. The exo-skeleton may assume contracted and enlarged conditions, and includes one or more serpentine elements, each extending both peripherally and axially along at least a portion of the peripheral wall. Coiled-sheet stents are provided on the ends of the tubular graft for anchoring the ends within a body passage. Each serpentine element is a zigzag structure extending peripherally about the peripheral wall, with a plurality of serpentine elements distributed axially along the peripheral wall. The serpentine elements are individually attached to the peripheral wall and/or connector elements may extend between adjacent serpentine elements. Alternatively, each serpentine element may define a generally sinusoidal shape extending axially along the peripheral wall. The tubular graft may have a bifurcated end from which a tubular graft extension segment may extend and to which a docking limb may be attached. A plurality of serpentine elements may also be attached to the extension segment and the docking limb.</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

DESCRIPTIONCoiled-Sheet Stent-Graft With Exo-SkeletonField Of The Invention

The present invention relates generally to prostheses
5 for implantation with body lumens, and more particularly to
a stent-graft having a flexible exo-skeleton attached to a
tubular graft.

Background

Graft prostheses are often implanted within blood
10 vessels, particularly the aorta or other arteries, which may
be subject to aneurysm formation and/or severe athero-
sclerotic disease which may involve multiple stenoses. For
example, an aortic aneurysm may develop in a patient, for
example, within the abdominal aorta at the aorto-iliac
15 bifurcation, requiring treatment before the vessel wall
ruptures. To repair a blood vessel damaged by such an
affliction, a procedure involving use of a graft prosthesis
is generally performed.

A number of graft prostheses have been suggested that
20 include a tubular graft attached to a stent. The tubular
graft may be a biocompatible porous or nonporous tubular
structure to which a stent structure, such as a wire mesh,
may be attached. The stent structure may be biased to
assume an enlarged configuration corresponding to a target
25 treatment site, but may be constrained in a contracted
condition to facilitate introduction into a patient's vascu-
lature. The graft prosthesis may be percutaneously
introduced in the contracted condition, advanced to a
treatment site within a blood vessel, and released to assume
30 the enlarged condition and repair and/or bypass the
treatment site.

One problem often associated with such prostheses is
effectively securing the tubular graft at the treatment
site. The released graft prosthesis may not sufficiently
35 engage the vessel wall adjacent the treatment site, possibly

resulting in the graft prosthesis moving after implantation, which may expose the damaged vessel wall. Plastically deformable expandable stent structures may be provided to attempt to more directly control the engagement between the graft prosthesis and the vessel wall. Such expandable structures, however, may require the use of a balloon or other expandable member to expand the stent structure to the enlarged condition, which may introduce risks of uneven stent structure expansion and/or balloon rupture.

In addition to plastically deformable stents, coiled-sheet stent structures have been suggested. Coiled-sheet stents may provide enhanced anchoring within the blood vessel because the size of the fully expanded stent may be more precisely controlled. A coiled-sheet stent, however, may be substantially rigid transverse to its longitudinal axis, potentially resulting in a less flexible graft prosthesis, which may not be implanted effectively in tortuous anatomical conditions.

Therefore, there is a need for an improved stent-graft that may provide improved flexibility, while still providing substantial anchoring within a blood vessel.

Summary Of The Invention

The present invention is directed to a stent-graft having an exo-skeleton attached to a tubular graft. In accordance with one aspect of the present invention, a stent-graft is provided that includes a tubular graft having a peripheral wall defining a periphery and a lumen therein, the lumen extending axially between first and second ends of the tubular graft. An exo-skeleton is attached to the peripheral wall, the exo-skeleton including one or more serpentine elements, each serpentine element extending both peripherally, i.e., in a manner which generally surrounds the wall which may be circular, elliptical or other suitable configuration, and axially along at least a portion of the peripheral wall. A stent is provided on the first and/or

second ends for substantially anchoring the ends within a body passage.

In a preferred form, each serpentine element is a zigzag structure extending peripherally about the peripheral wall of the tubular graft. More preferably, a plurality of serpentine elements are distributed axially along the peripheral wall for providing articulation of the tubular graft between adjacent serpentine elements. The serpentine elements may be individually attached to the peripheral wall and/or the serpentine elements may be connected to one another by one or more connector elements extending between adjacent serpentine elements.

In another preferred form, each serpentine element defines a generally sinusoidal shape extending axially along the peripheral wall. Preferably, a plurality of serpentine elements may be distributed substantially evenly about the periphery of the peripheral wall. Each of these serpentine elements preferably includes substantially transverse peripheral elements, adjacent transverse peripheral elements being connected by alternating curved elements, thereby defining the generally sinusoidal shape.

The exo-skeleton of the stent-graft is preferably directable between a contracted condition for facilitating introduction within a body passage and an enlarged condition for deployment within the body passage. The exo-skeleton may substantially support the tubular graft to hold the lumen of the tubular graft substantially open in the enlarged condition. In a preferred form, the exo-skeleton is radially compressible to the contracted condition and biased to assume the enlarged condition. Alternatively, the contracted condition of the exo-skeleton may be achieved by flattening and circumferentially rolling the exo-skeleton.

The tubular graft may be provided from a polymeric material, such as polyester, polytetrafluorethylene, dacron, teflon, and polyurethane. The exo-skeleton may be attached to the tubular graft by sutures, staples, wires, or an adhesive, or alternatively by thermal bonding, chemical

bonding, and ultrasonic bonding. The exo-skeleton may be formed from a metallic material, such as stainless steel or Nitinol, and may be a flat-coiled sheet with the one or more serpentine elements formed therein, or a wire formed into a serpentine shape.

In alternative forms, the first and second ends of the tubular graft may have similar cross-sections, or the first end of the tubular graft may have a cross-section that is substantially smaller than a cross-section of the second end of the tubular graft. In addition, the exo-skeleton may be attached to an exterior surface of the tubular graft, to an interior surface of the tubular graft, or embedded in the wall of the tubular graft.

In accordance with another aspect of the present invention, a stent-graft is provided for placement within a bifurcation that includes a first tubular graft segment having a first end and a second bifurcated end, the first tubular graft segment having a first peripheral wall. A second tubular graft segment extends from the second bifurcated end, the second tubular graft segment having a second peripheral wall. An exo-skeleton is attached to at least one of the first and second peripheral walls, the exo-skeleton including one or more serpentine elements, each serpentine element extending both peripherally and axially along at least a portion of the respective peripheral wall to which it is attached.

A coiled-sheet stent may be provided on the first end for substantially anchoring the first end within a body passage. Similarly, a coiled-sheet stent may be provided on the second tubular graft segment opposite the second end of the first tubular graft segment.

Preferably, the stent-graft also includes a third tubular graft segment attachable to the second bifurcated end, the third tubular graft segment having a third peripheral wall. The exo-skeleton also may include one or more serpentine elements attached to the third peripheral wall.

Thus, a stent-graft in accordance with the present invention may have a substantially flexible region that may conform substantially to the anatomy of a treatment site. Preferably, the flexible region is defined by an exo-skeleton attached to a tubular graft that includes one or more serpentine elements. The serpentine elements may facilitate articulation between adjacent serpentine elements, and/or may be sufficiently resilient and flexible to allow articulation, compression and/or expansion of the serpentine elements themselves.

Preferably, the stent-graft also includes sealing members, preferably coiled-sheet stents, attached to the ends of the tubular graft for substantially sealing and/or anchoring the ends of the tubular graft proximate the treatment site. Thus, the stent-graft may accommodate tortuous anatomy while still providing effective sealing and anchoring within a body passage.

Other objects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

Brief Description Of The Drawings

FIG. 1 shows a perspective view of a stent-graft with exo-skeleton in accordance with the present invention.

FIG. 2 is a side view detail of the stent-graft of FIG. 1, showing a first preferred embodiment of a plurality of serpentine elements defining the exo-skeleton.

FIGS. 3A and 3B are cross-sections of the stent-graft of FIG. 1, taken along line 3-3, and showing the stent-graft in contracted and enlarged conditions, respectively.

FIG. 4 is a perspective view of an alternative embodiment of a serpentine element attachable to a tubular graft (in phantom).

FIGS. 5A-5D are end views of a stent-graft in accordance with the present invention, showing a method for rolling the stent-graft into a contracted condition.

FIG. 6 is a perspective view of another embodiment of a stent-graft, having a tapered configuration.

FIG. 7 is a perspective view of still another embodiment of a stent-graft, having a bifurcated main segment, an extension segment and an attachable docking limb.

FIG. 8 is a cross-sectional view of an abdomen, showing a method for implanting a stent-graft across a bifurcation for treating an aneurysm at the bifurcation.

FIG. 9 is a side view of a fully stretchable stent for use with a stent-graft in accordance with the present invention.

FIGS. 10A and 10B are end and side views, respectively, of a stent with anti-buckling segment.

FIGS. 11A and 11B are side and perspective views, respectively, of a stent with stretchable ends.

Detailed Description Of The Preferred Embodiments

Turning now to the drawings, FIG. 1 shows a first preferred embodiment of a stent-graft 10 in accordance with the present invention that includes a tubular graft 12, an exo-skeleton 14, and first and second coiled-sheet stents 16, 18. The tubular graft 12 has first and second ends 20, 22 defining a longitudinal axis 24 therebetween and a peripheral wall 26 defining a periphery 28 and a lumen 30 therein. The tubular graft 12 may be formed from a variety of biocompatible materials, preferably a polymeric material, such as polyester, polytetrafluorethylene, dacron, teflon, and polyurethane.

The exo-skeleton 14 is attached to the peripheral wall 26 and includes a plurality of serpentine elements 32. The exo-skeleton 14 may be formed from a variety of semi-rigid materials, preferably a biocompatible metallic material, such as Nitinol or stainless steel. The material may be resiliently deformable, may exhibit shape memory properties and/or may be plastically deformable, as described further below, to facilitate articulation of the stent-graft 10,

and/or the collapse and/or expansion of the exo-skeleton 14 between a contracted condition and an enlarged condition. The exo-skeleton 14 may be formed from flat sheet material having the individual serpentine elements 32 etched, cut or
5 otherwise formed from the sheet material. Alternatively, the exo-skeleton 14 may be formed from wire-like materials, for example, by forming each serpentine element 32 from a single strand of wire.

The exo-skeleton 14 may be attached either to the
10 exterior of the peripheral wall 26, to the interior of the peripheral wall 26, or alternatively embedded in the peripheral wall 26, with the term "exo-skeleton" being intended to include any of these locations and not to be limited to one location over another. The exo-skeleton 14
15 may be attached by mechanical fasteners, such as sutures, wires, staples, and the like, by an adhesive, or by a bonding process, such as thermal bonding, chemical bonding, or ultrasonic bonding.

Each serpentine element 32 extends both "peripherally"
20 and "axially" along at least a portion of the peripheral wall 26. "Peripherally" refers to each serpentine element 32 extending in a manner which generally surrounds the peripheral wall 26 which preferably may be circular or elliptical, e.g., generally around the circumference or
25 other periphery of the peripheral wall 26, while "axially" refers to the serpentine element 32 extending along the peripheral wall 26 generally parallel to the longitudinal axis 24. Thus, each serpentine element 32 defines a generally "zigzag" shape made up, for example, of abrupt "Z"
30 and/or rounded "U" shaped elements integrally connected together.

In a first preferred form, shown in FIGS. 1 and 2, the serpentine elements 14 are defined by a plurality of zigzag elements, including generally straight axial regions 32a and
35 curved peripheral regions 32b, integrally formed together that extend substantially peripherally about the peripheral wall 26. The serpentine elements 32 consequently provide a

multi-cellular exo-skeleton 14 that may facilitate articulation between adjacent serpentine elements 32 when the stent-graft 10 is directed substantially transversely with respect to the longitudinal axis 24.

5 In one form, the serpentine elements 32 are connected by connector elements 34, which preferably extend substantially axially between adjacent serpentine elements 32. The connector elements 34 may be formed, etched or cut, when the serpentine elements are formed from a flat sheet,
10 or the connector elements 34 may be strands of wire attached to the serpentine elements 32 in a conventional manner. Alternatively, the serpentine elements 32 may be separate structures that are individually attached to the peripheral wall 26 of the tubular graft 12.

15 The coiled-sheet stents 16, 18 may be attached to the respective ends 20, 22 of the tubular graft, preferably to the interior of the peripheral wall 26, although alternatively the coiled-sheet stents 16, 18 may be provided as separate components from the tubular graft 12. The
20 coiled-sheet stents 16, 18 may expand automatically, but are preferably mechanically expandable, e.g., they may be ratchetable to larger diameters, for example, using a balloon or other expandable member (not shown).

The coiled-sheet stents 16, 18 may have a stretchable
25 design, a stretchable anti-buckling segment, and/or a stretchable crowning end. For example, as shown in FIG. 9, a fully stretchable coiled-sheet stent 410 is shown that is formed from a substantially flat mesh structure 412 defining individual resilient mesh elements 420 and having teeth 414
30 along a side edge 416 thereof for being received within the mesh elements 420. The mesh structure 412 may be rolled or coiled to define a longitudinal axis 418 and a circumference or periphery (not shown) in a plane substantially perpendicular to the longitudinal axis 418. The mesh
35 structure 412 may be formed from a plastically deformable material, such as stainless steel.

In a preferred form, however, the mesh structure 412 is formed from Nitinol or similar shape memory material, which has, for example, been polished and/or heat treated. In a free-stress state, e.g., the austenitic phase, the mesh elements 420 preferably define a "stretched" condition, i.e., expand about the periphery of the mesh structure 412 such that the mesh structure 412 is biased to assume an enlarged size, e.g., substantially similar to the cross-section of a vessel within which the stent 410 is to be implanted. The mesh elements 420 may adopt an "unstretched" configuration, i.e., may be compressed about the periphery of the mesh structure 412, such that the mesh structure 412 adopts a substantially reduced size. This may be achieved by transforming the Nitinol material of the mesh structure 412 to a martensitic phase, for example, upon cooling after heat treatment. The stent 410 may then be rolled and/or collapsed to a reduced delivery profile for attachment to a stent-graft, such as those described herein.

When the stent 410 is implanted within a blood vessel, the mesh structure 412 may stretch or return to its stress-free state, e.g., the austenitic phase, and expand to engage the vessel wall. If radial pressure is applied to the stent 410 by the vessel, the mesh elements 420 may be compressed about the periphery, thereby allowing the stent 410 to recoil and substantially eliminate the likelihood of the stent 410 buckling, as may occur when a conventional coiled-sheet stent is subjected to substantial radially compressive forces.

Turning to FIGS. 10A and 10B, another embodiment of a coiled-sheet stent 510 is shown that has a stretchable anti-buckling segment 512 formed from a mesh structure that is attached to a coiled-sheet portion 514. The coiled-sheet portion 514 includes teeth 516 along a side edge 518 and may be rolled or coiled to define overlapping inner and outer longitudinal sections 524, 526, a longitudinal axis 520 and a periphery 522 such that the anti-buckling segment 512 extends axially, i.e., substantially parallel to the

longitudinal axis 520. Similar to the previous embodiment, the anti-buckling segment 512 may be formed from Nitinol, which may be heat treated and stretched, and then cooled and unstretched. The axially oriented anti-buckling segment 512 facilitates the entire stent 510 recoiling when subjected to radially compressive forces by providing mesh elements 524 which may be compressed about the periphery 522, as described above. Thus, the stent 510 may combine the benefits of both a coiled-sheet stent, which is generally incompressible about its periphery, and a stretchable stent structure.

Turning to FIGS. 11A and 11B, another embodiment of a stent 610 is shown that includes an anti-buckling segment or "crowning end" 616 on one end 614 of a coiled-sheet portion 612. The coiled-sheet portion 612 and anti-buckling segment 616 include teeth 618a, 618b along a side edge 620 thereof, and may be rolled to define a longitudinal axis 622 and a perimeter 624. The anti-buckling segment 616 is preferably polished, heat treated into a desired shape, cooled and unstretched, and then coiled to its collapsed and rolled delivery profile. After being implanted, mesh elements 626 in the anti-buckling segment 616 may be compressed when the stent 610 is subjected to radially compressive forces, similar to the embodiments described above, thereby allowing the ends of the stent 610 to become tapered. Alternatively, the end 628 of the anti-buckling segment 616 may be flared outward (not shown) to thereby partially recoil under radially compressive forces such that the stent adopts a substantially uniform size upon implantation within a blood vessel.

The coiled-sheet stents 16, 18 may also include outwardly-oriented hooks or barbs (not shown) for enhancing anchoring of the stent-graft 10 within a body passage. Pro-thrombotic material (not shown) may be provided on the exterior surfaces of the coiled-sheet stents 16, 18, or alternatively on the ends 20, 22 of the tubular graft 12, to enhance sealing against the wall of the body passage.

Additional information on coiled sheet stents appropriate for use with a stent-graft in accordance with the present invention may be found in U.S. Patent Nos. 4,577,631 issued March 25, 1986 in the name of Kreamer, 5,007,926 issued April 16, 1991 in the name of Derbyshire, 5,158,548 issued October 28, 1992 in the name of Lau et al., Re 34,327 reissued July 27, 1993 in the name of Kreamer, 5,423,885 issued June 13, 1995 in the name of Williams, 5,441,515 issued August 15, 1995 in the name of Khosravi et al., and 5,443,500 issued August 22, 1995 in the name of Sigwart. The disclosures of these references and any others cited therein are expressly incorporated herein by reference.

Turning to FIGS. 3A and 3B, the stent-graft 10 may be radially compressible from an enlarged condition, shown in FIG. 3B, to a contracted condition, shown in FIG. 3A. In a preferred form, the exo-skeleton 14 may be resiliently biased to assume the enlarged condition, but may be constrained in the contracted condition to facilitate introduction of the stent-graft 10 into a patient's vasculature.

For example, the stent-graft 10 may be constrained in the contracted condition, and percutaneously introduced into a blood vessel (not shown). The stent-graft 10 may be advanced to a target treatment site, e.g., within the aorta or other blood vessel (not shown), and deployed, with the exo-skeleton 14 automatically expanding to the enlarged condition. The coiled-sheet stents 16, 18 may then be expanded to a desired size to substantially engage and anchor the ends 20, 22 of the tubular graft 12 in place proximate the treatment site. Alternatively, if the coiled-sheet stents 16, 18 are provided as separate components (not shown), they may be subsequently deployed and expanded to anchor the ends 20, 22 of the previously deployed tubular graft 12.

The exo-skeleton 14 may be retained in the contracted condition simply by applying a radial compressive force to the stent-graft 10 and constraining the stent-graft 10, for

example, within a sheath. Alternatively, if the exo-skeleton 14 is formed from Nitinol, the martensitic properties of the Nitinol may be used to substantially retain the stent-graft 10 in the contracted condition after
5 being radially compressed. The "zigzag" configuration of the serpentine elements 32 of the exo-skeleton 14 may facilitate substantially uniform radial compression of the stent-graft 10 when it is subjected to radially compressive forces, as shown in FIG. 3A, thereby minimizing the risk of
10 localized stress in the exo-skeleton 14 and/or the tubular graft 12.

When the exo-skeleton 14 automatically assumes the enlarged condition, the serpentine elements 32 preferably substantially expand and support the peripheral wall 26 of
15 the tubular graft 12, thereby maintaining the lumen 30 substantially open and unobstructed, as may be seen in FIG. 3B, for example, to facilitate blood flow through the treatment site being repaired. In an alternative form, the exo-skeleton 14 may be initially formed in the contracted
20 condition, but may be plastically deformable to the enlarged condition, for example, using a balloon or other expandable member after the stent-graft 10 has been deployed at the treatment site, as will be appreciated by those skilled in the art.

25 The multi-cellular configuration provided by the plurality of serpentine elements 32 of the exo-skeleton 14 may facilitate the stent-graft 10 conforming substantially to tortuous anatomy during advancement and/or upon deployment at a treatment site. If the stent-graft 10 is
30 subjected to substantially transverse forces, for example, when it is directed around a tightly curved region of a blood vessel, the stent-graft 10 may be easily articulated between adjacent serpentine elements 32 to conform to the shape of the blood vessel. In addition, the zigzag elements
35 of each serpentine element 32 may be resiliently deformable, thereby further facilitating conformance with local anatomic conditions. Thus, a stent-graft 10 in accordance with the

present invention may have a substantially flexible intermediate region 29 extending between substantially rigid anchoring stents 16, 18. The intermediate region 29 may allow the tubular graft 12 to conform to the anatomy of the treatment site, while the exo-skeleton 14 substantially supports the tubular graft 12 to prevent collapse or buckling.

Turning to FIG. 4, another preferred form of an exo-skeleton 114 is shown that includes one or more serpentine elements 132 attached to the peripheral wall 126 of a tubular graft 112 (in phantom) that extend substantially axially along the longitudinal axis 124 of a stent-graft 110. Each serpentine element 132 preferably defines a generally sinusoidal shape extending substantially axially along the peripheral wall 126, and includes substantially transverse peripheral elements 134, with adjacent peripheral elements 134 being connected by alternating curved elements 136 to define the generally sinusoidal shape.

In a preferred form, a plurality of serpentine elements 132 may be provided distributed substantially evenly about the periphery of the peripheral wall 126. For example, as shown in FIGS. 5A-5D, a pair of serpentine elements 132 may be attached to the peripheral wall 126 opposite one another.

Turning to FIGS. 5A-5D, a stent-graft 110 having a pair of axial serpentine elements 132a, 132b is shown being rolled from an enlarged condition to a contracted condition. The exo-skeleton 114 is preferably biased to assume the enlarged condition of FIG. 5A. Because of the spaces 133 extending substantially axially between the serpentine elements 132a, 132b, the stent-graft 110, including coiled-sheet stents (not shown) on the ends of the stent-graft 110, may be flattened, as shown in FIG. 5B. One edge of the stent-graft 110 may then be rolled, similar to a coiled-sheet stent, as shown in FIG. 5C, until the entire stent-graft 110 is fully rolled into the contracted condition, shown in FIG. 5D, thereby providing a reduced profile. The stent-graft 110 may then be retained in the contracted

condition to facilitate introduction into and advancement within a patient's vasculature, until deployed at a target treatment site, whereupon the stent-graft 110 may automatically expand to its enlarged condition.

5 Turning to FIG. 6, another preferred embodiment of a stent-graft 210 is shown, which has a substantially tapered configuration between its first and second ends 220, 222. Similar to the previous embodiments, the stent-graft 210 has a tubular graft 212 to which an exo-skeleton 214 is attached
10 to provide a resilient, flexible region. Coiled-sheet stents 216, 218 are attached to the ends 220, 222 of the tubular graft 212 for anchoring the ends 220, 222 within a body passage. The second end 222 of the tubular graft 212 has a diameter that is substantially smaller than the first
15 end 220 to conform substantially to the anatomy of a tapered blood vessel or to extend between a first larger vessel and a second smaller vessel.

Turning to FIG. 8, a tapered stent-graft 210, such as that just described, may be used in a method for repairing
20 an aortic aneurysm 250 that extends from an abdominal aorta 252 through a bifurcation 254 into the iliac arteries 256a, 256b. The stent-graft 210, in a contracted condition, may be introduced across the bifurcation 254 with the larger first end 220 oriented towards the abdominal aorta 252. For
25 example, the stent-graft 210 may be placed on a catheter delivery device (not shown), percutaneously introduced into a peripheral artery (not shown), advanced into the ipsilateral iliac artery 256a, and through the bifurcation 254 until the first end 220 reaches an undamaged region of
30 the abdominal aorta 252. The stent-graft 210 may be then deployed and expanded to its enlarged condition, for example, when the exo-skeleton 214 automatically expands upon deployment. Coiled-sheet stents 216, 218 on the stent-graft 210 may be expanded to substantially seal and anchor
35 the stent-graft 210 to undamaged regions of the abdominal aorta 252 and the ipsilateral iliac artery 256a, respectively.

The contralateral iliac artery 256b may be substantially permanently occluded with a vessel occluder 260, and a femoral-to-femoral bypass graft 270 may be attached between the femoral arteries 258, or alternatively
5 between the iliac arteries 256, to allow blood flow from the ipsilateral iliac artery 256a into the contralateral iliac artery 256b and beyond.

Turning to FIG. 7, a stent-graft 310 for repairing a bifurcation is shown, in accordance with another aspect of
10 the present invention. The stent-graft 310 includes a plurality of tubular segments, namely a first main segment 312, a second extension segment 314 extending from the first segment 312, and a third segment or "docking limb" 316 that is attachable to a collar 318 on the first segment 312. The
15 first segment 312 has a first end 320 and a second bifurcated end 322 defining a longitudinal axis 224 therebetween, with the second segment 314 and the collar 318 extending adjacent one another from the second bifurcated end 322.

20 The first and second segments 312, 314 have first and second peripheral walls 326, 328, respectively, which may be integrally formed together, or may be provided as separate wall portions that are attached to one another. The first peripheral wall 326 defines a lumen 330 that extends from
25 the first end 320 through the first segment 312 and is bifurcated into a first branch lumen 330a defined by the second peripheral wall 328 and a second branch lumen 330b at least partially defined by the collar 330b.

An exo-skeleton 332 is attached to at least one of the
30 first and second peripheral walls 326, 328 and/or the collar 318, which includes a plurality of serpentine elements 334, similar to the serpentine elements previously described herein. Preferably, a first set of serpentine elements 334a are attached to the first peripheral wall 326 to support the
35 first segment 312, and a second set of serpentine elements 334b are attached to the second peripheral wall 328 to support the second segment 314. The serpentine elements 334

may be individually attached to the respective peripheral walls 326, 328 and/or adjacent serpentine elements may be connected to one another by one or more connector elements (not shown), as described above.

5 A first coiled-sheet stent 336 is attached to the first end 320 for substantially anchoring and/or sealing the first end 320 within a body passage. Similarly, a second coiled-sheet stent 338 is attached to a distal end 340 of the second segment 314.

10 The docking limb 316 has a third peripheral wall 348 to which one or more serpentine elements 350 may be attached, thereby further defining the exo-skeleton 332 of the stent-graft 310. A third coiled-sheet stent 342 may be attached to a first or distal end 344 of the docking limb 316. A
15 second or proximal end 346 of the docking limb 316 is attachable to the collar 318 on the first segment 312, for example, by a lap connection, or alternatively using another coiled-sheet stent (not shown).

20 The exo-skeleton 332 may be directed between a contracted condition for facilitating introduction within a body passage and an enlarged condition for deployment within the body passage, similar to the stent-grafts previously described herein. For example, each serpentine element 334a, 334b, 350 may be radially compressible to its
25 contracted condition and biased to assume its enlarged condition.

30 In a preferred form, the first end 320 of the first segment 312 has a size in its enlarged condition that corresponds substantially to the diameter of an undamaged region of an abdominal aorta. The distal ends 340, 344 of the second segment 314 and the docking limb 316 have sizes in their enlarged conditions that are substantially smaller than the size of the first segment 312, preferably corresponding substantially to the diameter of an undamaged
35 region of an iliac artery.

 The first and second segments 312, 314 may be radially compressed into their contracted conditions and directed

within a patient's vasculature to a bifurcated treatment site, such as a site of an aneurysm at the aorto-iliac bifurcation (not shown), similar to that shown in FIG. 8. The first end 320 may be aligned with an undiseased region of the abdominal aorta proximate the aneurysm, with the second segment 314 extending into a first iliac artery and the collar 318 oriented towards a second iliac artery. The first and second segments 312, 314 may be deployed and expanded to their enlarged conditions, and the first and second coiled-sheet stents 336, 338 expanded to substantially engage the walls of the undiseased abdominal aorta and first iliac artery, respectively.

The docking limb 316, in its contracted condition, may be advanced into the second iliac artery, and the proximal end 346 aligned with the collar 318. The docking limb 316 may then be deployed and expanded to its enlarged condition such that the proximal end 346 substantially engages the collar 318. The third coiled-sheet stent 342 may be expanded to substantially seal and engage an undiseased region of the second iliac artery.

Thus, the damaged region of the aorto-iliac bifurcation may be completely bypassed using a stent-graft 310 in accordance with the present invention. The flexible exoskeleton 332 may allow the stent-graft 310 to conform substantially to the anatomy at the bifurcated treatment site, while supporting the tubular graft segments 312, 314, 316 to provide a substantially open and unobstructed lumen to accommodate the flow of blood therethrough. The coiled-sheet stents 336, 338, 342 may substantially anchor the respective ends 320, 340, 344 of the stent-graft 310 and/or substantially seal the stent-graft 310 to the walls of the vessels.

While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms

or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the appended claims.

Claims

1. A stent-graft, comprising:
a tubular graft having a peripheral wall defining a periphery and a lumen therein, the lumen extending axially
5 between first and second ends of the tubular graft;
an exo-skeleton attached to the peripheral wall, the exo-skeleton comprising one or more serpentine elements, each serpentine element extending both peripherally and axially along at least a portion of the peripheral wall; and
10 a stent on the first end for substantially anchoring the first end within a body passage.
2. The stent-graft of claim 1, wherein each serpentine element comprises a zigzag structure extending substantially peripherally about the peripheral wall of the
15 tubular graft.
3. The stent-graft of claim 2, further comprising a plurality of serpentine elements distributed axially along the peripheral wall for providing articulation of the tubular graft between adjacent serpentine elements.
- 20 4. The stent-graft of claim 3, wherein the plurality of serpentine elements are individually attached to the peripheral wall.
5. The stent-graft of claim 3, wherein the plurality of serpentine elements are connected to one another by one
25 or more connector elements extending between adjacent serpentine elements.
6. The stent-graft of claim 1, wherein each serpentine element defines a generally sinusoidal shape extending substantially axially along the peripheral wall.

7. The stent-graft of claim 6, further comprising a plurality of serpentine elements distributed substantially evenly about the periphery of the peripheral wall.

8. The stent-graft of claim 6, wherein each
5 serpentine element includes substantially transverse peripheral elements, adjacent transverse peripheral elements being connected by alternating curved elements, thereby defining the generally sinusoidal shape.

9. The stent-graft of claim 1, wherein the exo-
10 skeleton is directable between a contracted condition for facilitating introduction within a body passage and an enlarged condition for deployment within the body passage, the exo-skeleton substantially supporting the tubular graft to hold the lumen of the tubular graft substantially open in
15 the enlarged condition.

10. The stent-graft of claim 9, wherein the exo-skeleton is radially compressible to the contracted condition and biased to assume the enlarged condition.

11. The stent-graft of claim 9, wherein the contracted
20 condition of the exo-skeleton is achieved by substantially flattening and circumferentially rolling the exo-skeleton.

12. The stent-graft of claim 1, wherein the tubular graft comprises a polymeric material.

13. The stent-graft of claim 1, wherein the polymeric
25 material is selected from the group consisting of polyester, polytetrafluorethylene, dacron, teflon, and polyurethane.

14. The stent-graft of claim 1, wherein the exo-skeleton is attached to the tubular graft by sutures, staples, wires, or an adhesive.

15. The stent-graft of claim 1, wherein the exo-skeleton is attached to the tubular graft by a process selected from thermal bonding, chemical bonding, and ultrasonic bonding.

5 16. The stent-graft of claim 1, wherein the exo-skeleton comprises a flat-coiled sheet with the one or more serpentine elements formed therein.

10 17. The stent-graft of claim 1, wherein each serpentine element comprises a wire formed into a serpentine shape.

18. The stent-graft of claim 1, wherein the stent on the first end comprises a coiled-sheet stent.

15 19. The stent-graft of claim 1, wherein the stent includes external outwardly oriented hooks for engaging a wall of a body passage.

20. The stent-graft of claim 1, further comprising pro-thrombotic material on an exterior surface of at least the stent, or one of the first and second ends of the tubular graft.

20 21. The stent-graft of claim 1, wherein the first end of the tubular graft has a cross-section that is substantially smaller than a cross-section of the second end of the tubular graft.

25 22. The stent-graft of claim 1, wherein the exo-skeleton is attached to an exterior surface of the tubular graft.

23. A stent-graft, comprising:

a tubular graft having a peripheral wall defining a periphery and a lumen therein, the lumen extending axially between first and second ends of the tubular graft; and

5 a plurality of serpentine elements attached to and distributed axially along the peripheral wall in a predetermined configuration for providing articulation of the tubular graft between adjacent serpentine elements, each serpentine element defining a zigzag shape extending substantially peripherally about the peripheral wall of the
10 tubular graft.

24. The stent-graft of claim 23, further comprising a stent on at least one of the first and second ends.

25. The stent-graft of claim 24, wherein the stent comprises a plurality of resilient mesh elements, the mesh
15 elements being adapted to partially recoil when the stent is subjected to radially compressive forces.

26. The stent-graft of claim 25, wherein the entire stent is made of resilient mesh elements.

27. The stent-graft of claim 24, wherein the stent
20 comprises a coiled-sheet stent.

28. The stent-graft of claim 27, wherein the coiled-sheet stent comprises a stretchable portion defined by a plurality of resilient mesh elements adapted to partially recoil when the stent is subjected to radially compressive
25 forces.

29. The stent-graft of claim 28, wherein the stretchable portion extends longitudinally between first and second ends of the stent.

30. The stent-graft of claim 28, wherein the
30 stretchable portion comprises a sleeve on an end of the

coiled-sheet stent exposed beyond the respective end of the tubular graft.

31. The stent-graft of claim 23, wherein the plurality of serpentine elements are individually attached to the peripheral wall.

32. The stent-graft of claim 23, wherein the plurality of serpentine elements are connected to one another by one or more connector elements extending between adjacent serpentine elements.

33. The stent-graft of claim 23, wherein each serpentine element is directable between a contracted condition for facilitating introduction within a body passage and an enlarged condition for deployment within the body passage.

34. The stent-graft of claim 33, wherein each serpentine element is radially compressible to the contracted condition and biased to assume the enlarged condition.

35. The stent-graft of claim 23, wherein the second end of the tubular graft is bifurcated, and wherein the stent-graft further comprises:

a tubular graft extension segment extending from the second end, the tubular graft extension segment having a peripheral wall; and

a plurality of serpentine elements attached to and distributed along the peripheral wall of the tubular graft extension segment in a predetermined configuration for providing articulation of the tubular graft extension segment between adjacent serpentine elements.

36. The stent-graft of claim 35, further comprising:

a tubular graft docking limb having a peripheral wall, the docking limb being attachable to the second end of the tubular graft adjacent the tubular graft extension segment; and

5 a plurality of serpentine elements attached to and distributed along the peripheral wall of the tubular graft docking limb in a predetermined configuration for providing articulation of the tubular graft docking limb between adjacent serpentine elements.

10 37. A stent-graft for placement within a bifurcation, comprising:

a first tubular graft segment having a first end and a second bifurcated end, the first tubular graft segment having a first peripheral wall;

15 a second tubular graft segment extending from the second bifurcated end, the second tubular graft segment having a second peripheral wall; and

an exo-skeleton attached to at least one of the first and second peripheral walls, the exo-skeleton comprising one
20 or more serpentine elements, each serpentine element extending both peripherally and axially along at least a portion of the respective peripheral wall to which it is attached.

38. The stent-graft of claim 37, further comprising a
25 stent on the first end for substantially anchoring the first end within a body passage.

39. The stent-graft of claim 37, further comprising a stent on the second tubular graft segment opposite the second end of the first tubular graft segment.

30 40. The stent-graft of claim 37, further comprising a third tubular graft segment attachable to the second bifurcated end adjacent the second tubular graft segment,

the third tubular graft segment having a third peripheral wall.

41. The stent-graft of claim 40, wherein the exo-skeleton comprises one or more serpentine elements attached
5 to the third peripheral wall.

42. The stent-graft of claim 37, wherein the plurality of serpentine elements are individually attached to the respective peripheral wall.

43. The stent-graft of claim 37, wherein the plurality
10 of serpentine elements are connected to one another by one or more connector elements extending between adjacent serpentine elements.

44. The stent-graft of claim 37, wherein each serpentine element is directable between a contracted
15 condition for facilitating introduction within a body passage and an enlarged condition for deployment within the body passage.

45. The stent-graft of claim 44, wherein each serpentine element is radially compressible to the
20 contracted condition and biased to assume the enlarged condition.

46. A method for repairing an aneurysm at a bifurcation between a first main vessel and second and third branch vessels, comprising the steps of:
25 percutaneously introducing a stent-graft into a vessel in a contracted condition, the stent-graft comprising a flexible exo-skeleton attached to a tubular graft;
advancing the stent-graft across the bifurcation between undiseased portions of the first and second vessels;

expanding the stent-graft to an enlarged condition, the
exo-skeleton comprising serpentine elements retaining a
lumen of the tubular graft substantially open;

occluding the third vessel proximate the bifurcation;
5 and

implanting a bypass graft between the second and third
vessel downstream from the bifurcation.

47. A stretchable stent, comprising:

a coiled-up sheet having overlapping inner and outer
10 longitudinal sections, and being radially expandable between
a first size and one or more larger sizes, the coiled-up
sheet defining a periphery in a plane substantially
perpendicular to a longitudinal axis thereof;

a plurality of teeth extending from the inner
15 longitudinal section for engaging openings in the outer
longitudinal section to selectively secure the coiled-up
sheet in the one or more larger sizes; and

a stretchable portion comprising a plurality of
resilient mesh elements extending along a portion of the
20 coiled-up sheet, the mesh elements being adapted to
partially recoil about the periphery of the coiled-up sheet
when the stent is subjected to radially compressive forces.

48. The stent-graft of claim 47, wherein the
stretchable portion extends longitudinally between first and
25 second ends of the coiled-up sheet.

49. The stent-graft of claim 47, wherein the
stretchable portion comprises a sleeve on an end of the
coiled-up sheet.

50. The stent-graft of claim 47, wherein the coiled-up
30 sheet comprises Nitinol.

51. The stent-graft of claim 50, wherein the coiled-up
sheet is biased to adopt a second size larger than the first

size when the Nitinol is in its austenitic phase, whereby the mesh elements define a stretched configuration about the periphery of the coiled-up sheet.

52. The stent-graft of claim 50, wherein the coiled-up
5 sheet is biased to adopt a third size smaller than the second size when the Nitinol is in a martensitic phase, whereby the mesh elements define an unstretched configuration substantially smaller than the stretched configuration.

53. The stent-graft of claim 47, wherein the coiled-up
10 sheet comprises an unstretchable portion that is generally incompressible about the periphery.

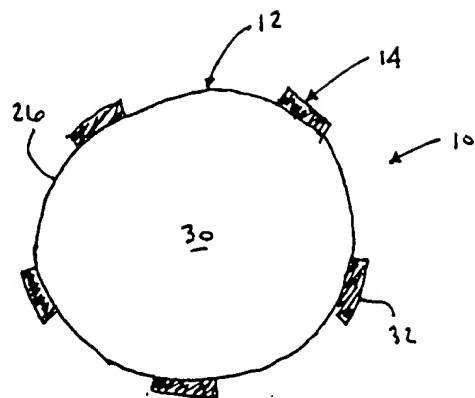
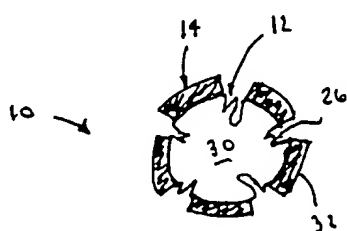
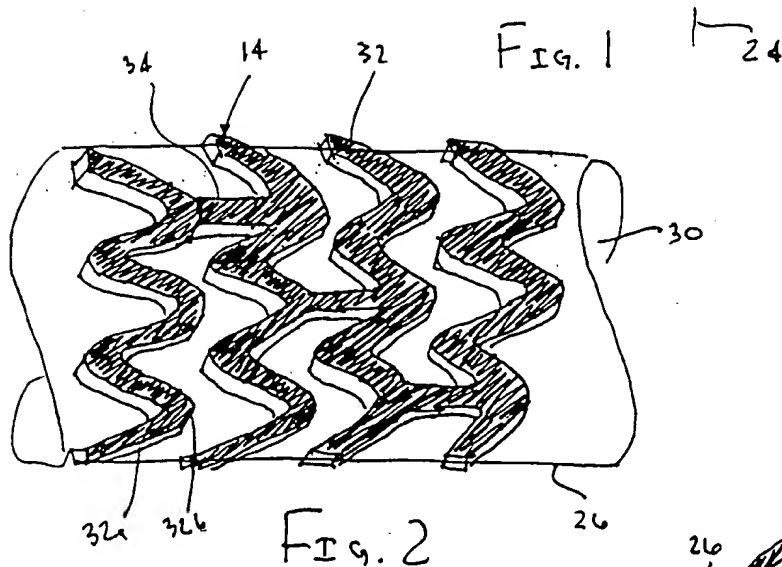
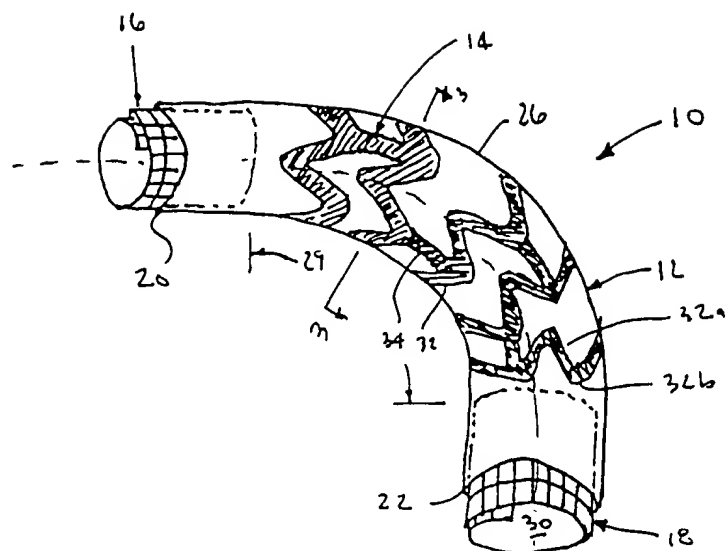


FIG. 3A

FIG. 3B

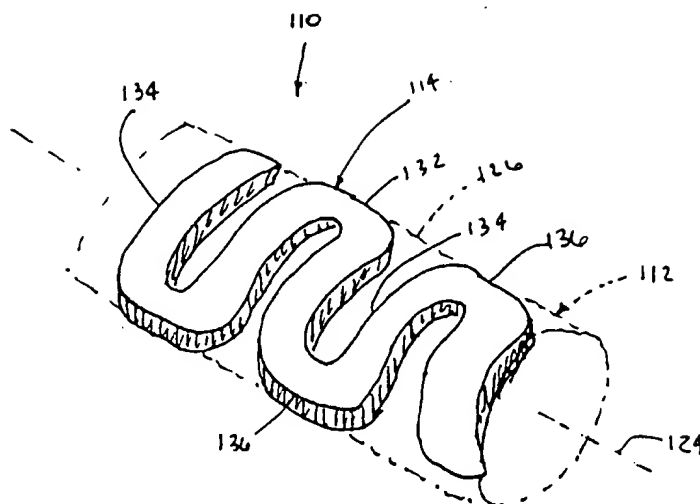


FIG. 4

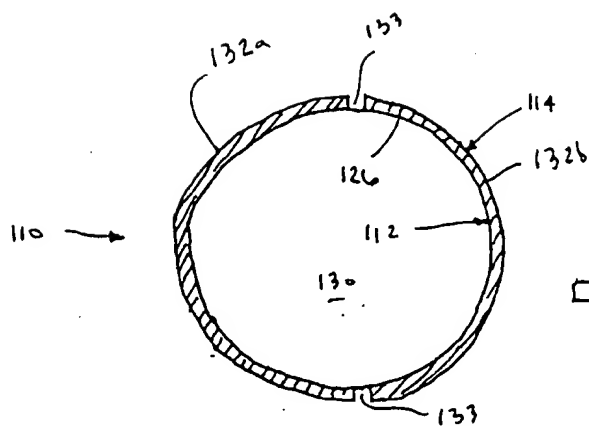


FIG. 5A

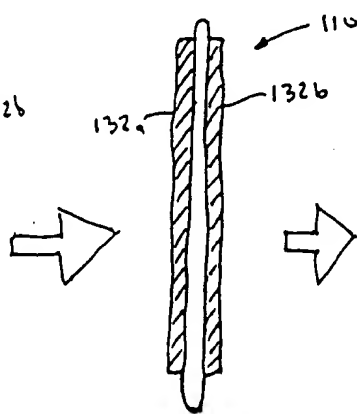


FIG. 5B

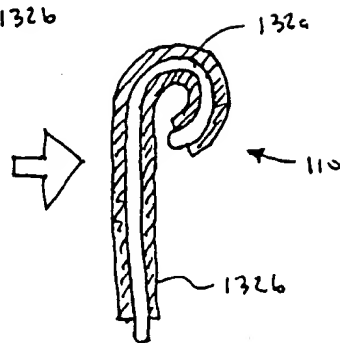


FIG. 5C

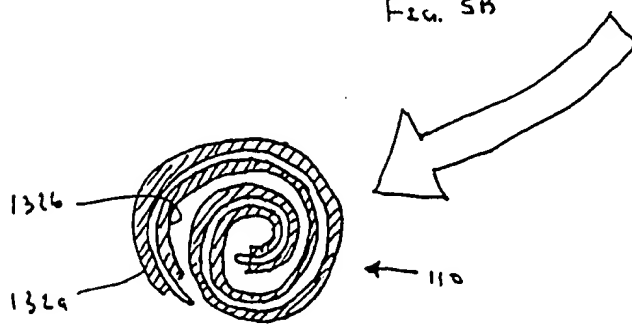


FIG. 5D

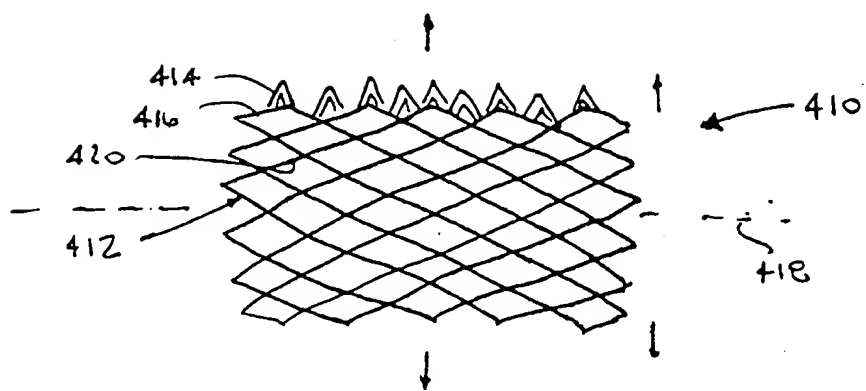


FIG. 9

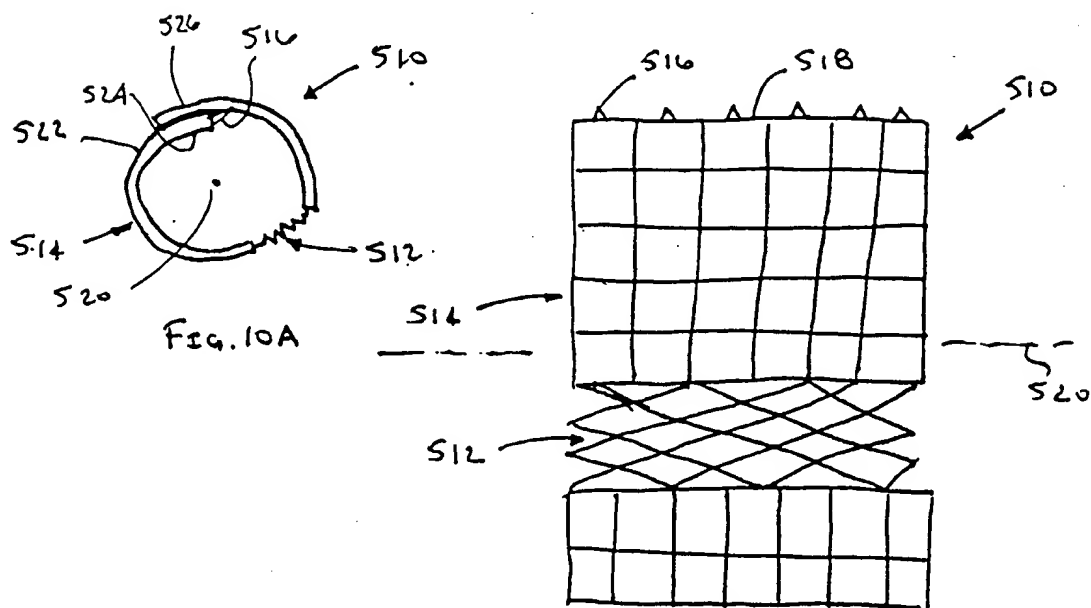


FIG. 10A

FIG. 10B

